

**Appl. No.** : **10/612,766**  
**Filed** : **July 2, 2003**

## **AMENDMENTS TO THE CLAIMS**

Please cancel Claims 26-28, 30, and 46-63.

1. (Original) A container comprising:

a body; and

a lid for closing the container to hermetically seal a product therein, said lid having a sealing rim including a layer of elastomeric material which sealingly engages with a sealing rim of the container body, and said elastomeric sealing material extending into the interior of the container beneath the lid to provide an elastomeric formation operative to engage an upper surface of the product within the container so as to apply a resilient bias thereto to hold a lower face of the product against the base of the container.

2. (Original) A container according to claim 1, wherein the sealing engagement provides a first, static, seal and a second, dynamic, seal.

3. (Original) A container according to claim 2, wherein the static seal provides a locking action to releasably lock the lid to the sealing rim of the container body.

4. (Original) A container according to claim 1, wherein the sealing rim of the lid is of inverted channel section to which the layer of elastomeric material is applied, the elastomeric layer including a formation which engages against a formation on the sealing rim of the container body to provide therewith a static seal and the elastomeric layer also having a lip to slidably engage a surface of the sealing rim of the container to provide a dynamic seal.

5. (Original) A container according to claim 4, wherein the lip forming the dynamic seal slidably engages an inner surface of the sealing rim of the container body.

6. (Original) A container according to claim 5, wherein the formation providing the static seal is an inwardly directed lip lockably and sealingly engageable with an outwardly directed lip on the sealing rim of the container body.

7. (Original) A container according to claim 4, wherein a further sealing zone is formed between an upper end edge of the sealing rim of the container body and the immediately adjacent part of the elastomeric layer.

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8. (Original) A container according to claim 1, wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

9. (Original) A container according to claim 1, wherein the container is of approximately rectangular shape and opening of the container is effected by a set of first and second co-operating lugs at one of the corner portions of the container, the first lug forming part of the lid and the second lug forming part of the container body with the two cooperating lugs being side by side such that opening can be effected by lifting the first lug while pushing down on the second lug.

10. (Original) A container according to claim 1 having a facility to effect pressure relief within the interior of the container when hermetically sealed whereby to compensate for pressure variation over a temperature range to embrace sterilisation temperatures and freezing temperatures.

11. (Original) A container according to claim 1 for containing a product which is at least partially manufactured within the container by being subject at least to freeze drying within the container, wherein to facilitate freeze drying the lid is able to be applied to the container body but not fully sealed thereto to thereby permit the withdrawal of moisture during freeze drying.

12. (Original) A container according to claim 11, wherein the container includes means for releasably locking the lid in a first position with its sealing rim raised from the sealing rim of the container body sufficient to enable withdrawal of moisture from the interior of the container during freeze drying.

13. (Original) A container according to claim 12, wherein in said first position the sealing rim of the lid is uniformly spaced above the sealing rim of the container body such that after freeze drying has been completed the lid can be pushed downwardly to release the locking force and to move its sealing rim downwardly into sealing engagement with the sealing

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rim of the body, or the container body is able to be moved upwardly relative to the lid to achieve that effect.

14. (Original) A container according to claim 13, wherein the lid is releasably retained in its freeze drying position by releasable locking lugs such that upon release of the locking effect provided thereby, the lugs also act to guide the lid into its hermetically sealed position.

15. (Original) A container according to claim 11, wherein to facilitate freeze drying, the lid has a part in sealing relation to the body with another part of the lid being in a position to permit escape of moisture, and when drying is complete that latter part can then be moved into a position in which the container is hermetically sealed.

16. (Original) A container according to claim 11, wherein to provide effective heat transfer during freeze drying the outer surface of the container base is substantially planar to achieve large area surface contact with the surface of a freezing shelf of a freeze drier.

17. (Original) A container comprising:

a body; and

a lid for closing the container to hermetically seal a product therein, said lid having a sealing rim including a layer of elastomeric material which sealingly engages with a sealing rim of the container body, the sealing engagement providing a first, static, seal and a second, dynamic, seal and said elastomeric sealing material extending into the interior of the container beneath the lid to provide an elastomeric formation operative to engage an upper surface of the product within the container so as to apply a resilient bias thereto to hold a lower face of the product against the base of the container, wherein the elastomeric formation acts to inhibit movement of the product within the container, and the elastomeric formation flexes to accommodate a range of product thicknesses and/or surface irregularities.

18. (Original) A container according to claim 17, wherein the elastomeric formation is annular.

19. (Original) A container according to claim 17, wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding

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outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

20. (Original) A container according to claim 17, having a facility to effect pressure relief within the interior of the container when hermetically sealed whereby to compensate for pressure variation over a temperature range to embrace sterilisation temperatures and freezing temperatures, wherein the pressure relief facility is provided by a deformable wall portion of at least one of the body and lid.

21. (Original) A container according to claim 20, wherein the deformable wall portion is provided in the lid and comprises a bellows-like flexible wall structure in the lid.

22. (Currently Amended) A container for a pharmaceutical product to protect the product against physical damage, said container comprising a body for housing the product and a lid for closing the container to provide a hermetically sealed enclosure for the product therein, said container having a facility for providing internal pressure relief over a range of temperatures encompassing freezing to sterilizing to permit maintenance of the hermetic seal throughout the freezing to sterilizing temperatures to which the container will be exposed wherein the body and lid comprise a robust semi-rigid polymer of pharmaceutical grade and wherein the hermetic seal between co-operating parts of the body and lid is formed by an elastomeric layer therebetween wherein the elastomeric layer is applied to a peripheral rim of the lid to sealingly co-operate with a peripheral sealing rim of the body wherein the sealing co-operation between the elastomeric layer and the sealing rim of the body provides a first, static, seal and a second, dynamic, seal and wherein the elastomeric sealing layer applied to the lid extends inwardly of a sealing zone into the interior of the container beneath the lid to provide a resilient formation to engage the product within the container and apply a resilient bias thereto in a direction towards an opposing base of the container so as to urge the product against the base and thereby to maintain the product against movement within the container.

23. (Currently Amended) A container according to claim 22, wherein the pressure relief facility is provided by a deformable wall portion at ~~lest~~ least one of the container body and lid.

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24. (Original) A container according to claim 23, wherein the deformable wall portion is provided in the lid and comprises a bellows flexible wall structure in the lid.

25. (Original) A container according to claim 23, wherein the range over which the pressure relief facility is effective includes 150°C.

26. (Cancelled)

27. (Cancelled)

28. (Cancelled)

29. (Currently Amended) A container according to claim 28 22, wherein the static seal provides a locking action to releasably lock the lid to the sealing rim of the container body.

30. (Cancelled)

31. (Currently Amended) A container according to claim 30 22, wherein the resilient formation acts to inhibit movement of the product within the container, and the resilient formation flexes to accommodate at least one of a range of product thicknesses and surface irregularities.

32. (Original) A container according to claim 31, wherein the resilient formation is annular.

33. (Currently Amended) A container according to claim 27 22, for containing a product which is at least partially manufactured within the container by being subject at least to freeze drying within the container, wherein to facilitate freeze drying the lid is able to be applied to the container body but not fully sealed thereto to thereby permit the withdrawal of moisture during freeze drying.

34. (Original) A container according to claim 33, wherein the container includes means for releasably locking the lid in a first position with its sealing rim raised from the sealing rim of the container body sufficient to enable withdrawal of moisture from the interior of the container during freeze drying.

35. (Original) A container according to claim 34, wherein in said first position the sealing rim of the lid is uniformly spaced above the sealing rim of the container body such that after freeze drying has been completed the lid can be pushed downwardly to release the locking force and to move its sealing rim downwardly into sealing engagement with the sealing

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rim of the body, or the container body is able to be moved upwardly relative to the lid to achieve that effect.

36. (Original) A container according to claim 35, wherein the lid is releasably retained in its freeze drying position by releasable locking lugs such that upon release of the locking effect provided thereby, the lugs also act to guide the lid into its hermetically sealed position.

37. (Original) A container according to claim 33, wherein to facilitate freeze drying, the lid has a part in sealing relation to the body with another part of the lid being in a position to permit escape of moisture, and when drying is complete that latter part can then be moved into a position in which the container is hermetically sealed.

38. (Original) A container according to claim 33, wherein to provide effective heat transfer during freeze drying the outer surface of the container base is substantially planar to achieve large area surface contact with the surface of a freezing shelf of a freeze drier.

39. (Original) A container according to claim 22, wherein the container is of approximately rectangular shape and opening of the container is effected by a set of co-operating first and second lugs at one of the corner portions of the container, the first lug forming part of the lid and the second lug forming part of the container body with the two lugs being side by side such that opening can be effected by lifting the first lug while pushing down on the second lug.

40. (Original) A container according to claim 39, wherein a second set of co-operating first and second lugs is also provided at the diagonally opposite corner portion.

41. (Currently Amended) A container ~~according to claim 27, for a pharmaceutical product to protect the product against physical damage, said container comprising a body for housing the product and a lid for closing the container to provide a hermetically sealed enclosure for the product therein, said container having a facility for providing internal pressure relief over a range of temperatures encompassing freezing to sterilizing to permit maintenance of the hermetic seal throughout the freezing to sterilizing temperatures to which the container will be exposed and wherein the body and lid comprise a robust semi-rigid polymer of pharmaceutical grade and wherein the hermetic seal between co-operating parts of the body and lid is formed by an elastomeric layer therebetween and wherein the elastomeric layer is applied to a peripheral rim of the lid to sealingly co-operate with a peripheral sealing rim of the body and wherein the~~

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sealing rim of the lid is of inverted channel section to which the layer of elastomeric material is applied, the elastomeric layer including a formation which engages against a formation on the sealing rim of the container body to provide therewith a static seal and the elastomeric layer also having a lip to slidably engage a surface of the sealing rim of the container body to provide a dynamic seal.

42. (Original) A container according to claim 41, wherein the lip forming the dynamic seal slidably engages an inner surface of the sealing rim of the container body.

43. (Original) A container according to claim 42, wherein the formation providing the static seal is an inwardly directed lip lockably and sealingly engageable with an outwardly directed lip on the sealing rim of the container body.

44. (Original) A container according to 43, wherein a further sealing zone is formed between an upper end edge of the sealing rim of the container body and the immediately adjacent part of the elastomeric layer.

45. (Currently Amended) A container according to claim 27, for a pharmaceutical product to protect the product against physical damage, said container comprising a body for housing the product and a lid for closing the container to provide a hermetically sealed enclosure for the product therein, said container having a facility for providing internal pressure relief over a range of temperatures encompassing freezing to sterilizing to permit maintenance of the hermetic seal throughout the freezing to sterilizing temperatures to which the container will be exposed and wherein the body and lid comprise a robust semi-rigid polymer of pharmaceutical grade and wherein the hermetic seal between co-operating parts of the body and lid is formed by an elastomeric layer therebetween and wherein the elastomeric layer is applied to a peripheral rim of the lid to sealingly co-operate with a peripheral sealing rim of the body and wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

46.-63. (Cancelled)